UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA v. 1) AMY WINSLOW, 2) MOHAMMAD HOSSEIN MALEKNIA, and 3) REBA DAOUST, Defendants.	)	Case No. 23-cr-10094-PBS

GOVERNMENT'S TRIAL BRIEF

The United States submits this brief in advance of trial, which is scheduled to commence on April 7, 2025.

I. Case Summary

The company and its devices

Magellan Diagnostics, Inc., headquartered in Billerica, Massachusetts, is the nation's leading manufacturer of medical devices for testing lead levels in the blood of children and adults. During the relevant time, Magellan's stable of blood lead level testing devices included LeadCare II, LeadCare Ultra, and LeadCare Plus.

LeadCare II (2006)
Point-of-care device that analyzed fingerstick and venous samples.

LeadCare Ultra (2013)
High-volume lab instrument that analyzed venous and fingerstick samples.

LeadCare Plus (2015)
Small-volume lab instrument that analyzed venous and fingerstick samples.

Each of the LeadCare devices works by collecting a blood sample—either from a vein, known as a venous test, or through a finger-stick, known as a capillary test—and mixing the sample with a chemical, called a treatment reagent, that separates lead from red blood cells so that it can be detected. That mixture is placed onto a sensor that goes into the Magellan device for a blood lead level reading.

According to the Centers for Disease Control and Prevention (CDC), there is no safe level of lead in the blood. Further, as reflected on Magellan's LeadCare devices' package inserts, "childhood lead poisoning is a major, preventable problem in the United States. Numerous studies have shown that exposure to lead can result in damage to the nervous, hematopoietic, endocrine, renal, and reproductive systems causing irreversible lifelong physical and mental health problems. Children are particularly susceptible to the effects of lead as their nervous systems are still developing." Lead exposure may damage children's ability to learn, ability to pay attention, and academic achievement. High levels of lead exposure attack the brain and central nervous system and may cause coma, convulsions, and even death. Accurate testing and monitoring of blood lead levels is an important part of lead poisoning prevention efforts.

In 2012, the CDC introduced a medical threshold at blood lead levels of 5 micrograms per deciliter to identify children and adults who have elevated blood lead levels. At that level, the CDC recommended that healthcare providers obtain from their patients an environmental exposure history to identify potential sources of lead and arrange for an environmental investigation of the patient's home to check the environment for possible causes of lead exposure and recommend ways to prevent further lead exposure. The CDC also recommended follow-up lead testing at recommended intervals for children with levels of 5 micrograms per deciliter or higher. If the blood lead test result was below 5, doctors typically would not intervene in this way. The CDC

recommended additional interventions by doctors, including hospitalization, at higher blood lead level thresholds.

The defendants

Defendant Amy Winslow was appointed Magellan's President and CEO in 2011. In 2012, defendant Hossein Maleknia joined Magellan as Chief Operating Officer and Vice President of Operations and soon hired defendant Reba Daoust as Manager and Director of Quality Assurance and Regulatory Affairs. By the time the defendants joined Magellan, LeadCare II was a well-established legacy product for point-of-care (mostly pediatricians' offices) blood lead testing, and it had obtained significant market share of blood lead tests conducted in the United States. None of the defendants was involved in the FDA submission and approval process when LeadCare II was cleared in 2006, but all of the defendants were involved in Magellan's testing, application for FDA clearance, and sales launch of the LeadCare Ultra device in 2012-2013.

LeadCare Ultra application for FDA clearance (November 2012)

In November 2012, Magellan sought clearance from the FDA to market the LeadCare Ultra, which was intended for laboratory use in testing blood lead levels. Instead of seeking pre-market approval as a new device, Magellan submitted a traditional 510(k) application[1] for LeadCare Ultra, claiming that it was substantially equivalent to the already-cleared LeadCare II device, which was used primarily in doctors' offices. Daoust had primary responsibility over regulatory affairs and was one of a handful of individuals at the company in charge of clinical testing and FDA submissions. Winslow and Maleknia were aware of and involved in Magellan's FDA submissions and both knew how important LeadCare Ultra's market success was to

[1] Such applications are authorized by Section 510(k) of the Food, Drug, and Cosmetics Act, 21 U.S.C. Chapter 9.

Magellan's private equity owners, who had tasked Winslow and Maleknia with positioning Magellan for sale.

Discovery of the Malfunction (June 2013)

In January 2013, the FDA put Magellan's LeadCare Ultra 510(k) application on hold and requested additional studies, including studies about how the device performed under different temperature and humidity conditions. In June 2013, while performing the FDA-requested studies, Magellan discovered a malfunction[2] affecting the LeadCare Ultra device (the "Malfunction") that caused blood lead test values to be lower than actual values under certain conditions. Specifically, lead values tended to be lower than the reference standard when blood samples were tested immediately and would rise over time as the blood samples incubated in treatment reagent. These results were contrary to the device's label, which promised an accurate result if the samples were tested immediately, without any incubation. Daoust was one of the first employees to learn about the Malfunction. She informed Winslow and Maleknia about the Malfunction the day after she received the unexpectedly and consistently low blood lead value results, but none of the defendants ever reported the results to the FDA. Instead, Magellan conceived a different temperature and humidity study, which did not contain any actual blood lead measurements, and reported those results to the FDA as part of the LeadCare Ultra 510(k) application. The FDA—unaware of the Malfunction—cleared LeadCare Ultra for marketing and distribution in August of 2013. However, the defendants—concerned about the Malfunction—delayed the planned LeadCare Ultra market launch to conduct further tests.

[2] "***Malfunction*** means the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed, as defined in § 801.4 of this chapter." 21 C.F.R. § 803.3(k) (emphasis in original).

LeadCare Ultra launch (December 2013) and customer complaints (August 2014)

After multiple tests confirming the Malfunction, and tests indicating that the Malfunction also affected the already cleared and widely used LeadCare II device, Magellan released LeadCare Ultra for sale to customers in December of 2013. The defendants did not notify potential customers or the FDA about the Malfunction prior to the release of LeadCare Ultra, nor did it notify the FDA or its LeadCare II customers that the Malfunction also affected LeadCare II, which had been on the market since 2006.

In August 2014, three LeadCare Ultra customers notified Magellan that they were getting false low results when they tested immediately but that the lead values went up over time. In other words, the customers were complaining that they were seeing the Malfunction that the defendants first observed in June of 2013. Continuing through October 2014, Magellan received similar complaints from other customers, who reported inaccurate lead test results, test results that were significantly lower than expected, and false lows below CDC's medical thresholds when the samples were tested immediately. The defendants ordered further internal tests, which confirmed the Malfunction and indicated that incubating (i.e., letting the blood sample/treatment reagent mixture rest) for at least 24 hours before testing was necessary to produce accurate results, but even that lengthy period of incubation did not solve the problem in all cases.

LeadCare Ultra customer letter (November 2014)

On November 24, 2014, Magellan's Marketing Director sent LeadCare Ultra customers a letter about the Malfunction, which was drafted by Daoust, edited by Winslow, and approved by Maleknia. The letter contained several false and misleading statements that misrepresented the frequency of the error and when Magellan discovered the Malfunction. The letter also advised customers to incubate the blood sample/treatment reagent mixture for 24 hours before running the

test—a significant change to the LeadCare Ultra's product label, which allowed immediate testing upon mixing the blood sample and treatment reagent. The FDA later found that Magellan's own studies did not support the claim that the 24-hour incubation period sufficiently mitigated the problem. The defendants did not notify the FDA about the Malfunction when they sent the customer letter, much less get the FDA's approval for the change of instructions.

Significantly late filing of the LeadCare Ultra MDR (April 2015)

Magellan finally notified the FDA about the Malfunction and the company's unilateral, unapproved change to LeadCare Ultra's user instructions in April 2015, after an outside consultant learned of the Malfunction and threatened to tell the FDA if Magellan did not. The Medical Device Report (MDR)[3] Magellan submitted to the FDA was false and misleading in several ways. First, like the November 2014 customer letter, the MDR concealed the severity and prevalence of the Malfunction and when Magellan first learned of it. Second, the MDR misrepresented the reason for the late submission. Third, the MDR misrepresented the number of complaining customers. And fourth, the MDR falsely represented that 24 hours' incubation was a complete mitigation for the Malfunction.[4]

[3] An MDR is one of the postmarket surveillance tools the FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. *See* https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems (last accessed on January 30, 2025).

[4] The FDA received hundreds of thousands of MDRs in 2015, and this MDR did not receive sufficient attention for various reasons. As a result, the FDA did not follow up with Magellan at the time. *See, e.g.*, https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems (last accessed on January 30, 2025) ("[A]lthough MDRs are a valuable source of information, this passive surveillance system has limitations. The incidence, prevalence, or cause of an event cannot be determined from this reporting system alone due to under-reporting of events, inaccuracies in reports, lack of verification that the device caused the reported event, and lack of information about frequency of device use.").

Discovery of possible root cause (Summer 2015)

A few months later, in the summer of 2015, Magellan identified what it believed was a possible root cause of the Malfunction: a substance in the rubber stopper of commonly used test tubes manufactured by Becton Dickinson (referred to as Brand X in the Indictment) interfered with the LeadCare devices' ability to detect lead accurately and caused test results to be lower than expected.

Sale of Magellan to Meridian Bioscience (March 2016)

Also in the summer of 2015, private-equity-owned Magellan engaged an investment bank with intent to sell the company. Magellan's board of directors tasked Winslow and Maleknia with increasing Magellan's value to better position the company for sale—by expanding its LeadCare product line, enlarging its market share for LeadCare II, and developing new blood testing devices—and linked their performance to lucrative financial incentives. In March 2016, Meridian Bioscience, Inc., acquired Magellan for $66 million. In connection with the sale, Winslow and Maleknia received bonuses of approximately $2 million and $400,000, respectively.

Significantly late notification to FDA about LeadCare II malfunction (November 2016)

In November 2016, after the sale to Meridian, over three years after the defendants first discovered the Malfunction in LeadCare II, and more than two years after conducting additional internal studies that confirmed the appearance of the Malfunction in LeadCare II and LeadCare Ultra, the defendants finally notified the FDA and some customers that the Malfunction also impacted LeadCare II. In doing so, however, they made false and misleading statements about when they discovered the problem in LeadCare II. Daoust authored a cover letter and MDR falsely stating that LeadCare II did not originally exhibit the issue and it was only after Magellan identified

the root cause of the problem in LeadCare Ultra that it checked to see if LeadCare II was also impacted.

Recall of the LeadCare devices (May 2017)

In March 2017, Magellan filed a special 510(k) application to change the labels for LeadCare Ultra and a new product, LeadCare Plus, to allow customers to test the blood-reagent mixture after either 24 hours of incubation or just one hour of incubation if the sample was heated to 60° C. The application triggered urgent questions from the FDA about the Malfunction and its effect on the accuracy and safety of LeadCare devices.

The FDA was particularly focused on when Magellan first discovered the Malfunction, because the date of discovery determined the number of patients who could have received false test results. During an April 20, 2017 conference call, an FDA official asked Magellan representatives when Magellan first discovered the Malfunction. Based on input from Daoust and Maleknia before the call, and at the direction of Daoust during the call, a Magellan consultant falsely told the FDA that Magellan had first discovered the problem in late 2014 after receiving customer complaints.

The FDA ultimately found that Magellan's own data showed that the LeadCare devices could not accurately measure lead levels in blood samples drawn from a vein, regardless of the recommended incubation times. In May 2017, the FDA recommended a Class I recall—the most serious recall—of all LeadCare devices using venous samples and warned the public not to use them for venous samples because of the Malfunction.[5]

[5] The recall was limited to venous samples because Magellan told the FDA that their studies showed the Malfunction did not occur in capillary (fingerstick) samples.

II. Evidence

The government expects to present the following categories of evidence at trial, subject to revision based on ongoing witness preparation and trial planning.

A. Witnesses[6]

1. Federal agency witnesses

In addition to the testimony of Dr. Adrienne Ettinger (CDC) and Dr. Courtney Lias (FDA), which was described and discussed in detail in connection with the *Daubert* motions, the government expects other current and former FDA employees to testify about their involvement with Magellan and communications with the defendants. Those potential witnesses include:

- Matthew Humbard, a senior FDA employee involved with the FDA's recall investigation in 2017, who is expected to testify, among other things, about the potential impact on FDA decision-making from false statements that Magellan representatives, including Daoust, made about the Malfunction to the FDA during the above-referenced call on April 20, 2017, that was recorded by Magellan; and
- Ian Pilcher, an FDA inspector present for the for-cause, on-site inspection of Magellan after the 2017 recall, who is expected to testify about information discovered during the inspection and statements made by Winslow, Maleknia, and Daoust in response to questions about the Malfunction.

2. Former Magellan employees/consultants

The government expects several former Magellan employees and consultants to testify about the work they performed on LeadCare devices, particularly in relation to the Malfunction, and their communications with the defendants. Potential witnesses include:

[6] The government provided its witness list to the defendants on December 20, 2024.

- Rosemary Feeney, former Research and Development Manager and Project Leader for LeadCare Ultra, who is expected to testify about how and when the Malfunction was initially discovered; tests she designed and conducted to identify the root cause of, and mitigate the impact of, the Malfunction; her involvement with Magellan's regulatory submissions to the FDA and communications to customers about the Malfunction; and statements made by Winslow, Maleknia, and Daoust about the Malfunction;
- Mike West, former product support and sales/marketing representative, who is expected to testify about the experiment he ran in June 2013 that revealed the Malfunction; his communications with other Magellan employees about the Malfunction; and statements made by Winslow, Maleknia, and Daoust about the Malfunction;
- Susan Garramone, former Research and Development scientist for LeadCare devices, who is expected to testify about how and when the Malfunction was initially discovered; tests she designed and conducted to identify the root cause of, and mitigate the impact of, the Malfunction; and statements made by Winslow, Maleknia, and Daoust about the Malfunction;
- Jan Krouwer, a statistics consultant hired by Magellan, who is expected to testify that, after he reviewed data provided by Magellan relating to the Malfunction, he told the defendants that if they did not report the Malfunction to the FDA, he would;
- Marcia Zucker, a regulatory consultant hired by Magellan, who is expected to testify about the advice she provided to the defendants about their regulatory obligations in connection with the Malfunction; her involvement in communicating to the FDA and customers about the Malfunction; and statements made by Winslow, Maleknia, and Daoust about the Malfunction; and

- Liesl Sheehan, a public relations consultant hired by Magellan, who is expected to testify about preparing for and traveling to Washington, DC with Winslow to brief congressional staffers after the 2017 recall, and about false and/or misleading statements Winslow made during the briefings.

3. Magellan customer witnesses

The government expects to call witnesses who used Magellan LeadCare devices in their professional capacity. Potential witnesses include:

- Dr. Hong Lee, clinical chemist for Northshore (IL) Health System (Charged Wire Fraud Count 2), who is expected to testify that she immediately stopped using LeadCare Ultra after she received the recall notice in 2017, and that she would have stopped using the device sooner if she had known about the Malfunction sooner;
- Charity Kamau, Nienke de Wilde, or Elsa Tran, employees of Medecins Sans Frontieres (MSF)/Doctors Without Borders (Charged Wire Fraud Count 3), who are expected to testify about MSF's purchase and use of LeadCare II in Africa, and the false and/or misleading nature of statements made by Magellan employees, including Winslow and Daoust, about the Malfunction and when it was discovered and how it was communicated to customers; and
- Lindsay Gauthier, a lab manager for Cambridge (MA) Hospital, who is expected to testify about her lab's involvement in Magellan's pre-clearance clinical studies and post-clearance requests for patient samples for LeadCare Ultra, and that she would not have recommended her lab purchase LeadCare Ultra in 2014 if she had known that the Malfunction had been discovered in 2013, months before the company released the device for sale.

4. Witnesses involved in the sale of Magellan to Meridian

The government expects to call witnesses who participated in the sale of Magellan to Meridian Bioscience, Inc. in 2015-2016. Potential witnesses include:

- Bryan Lookatch, an investment banker representing Magellan in the sale of the company, who is expected to testify that full disclosure of the severity and impact of the Malfunction would have impeded the sale of Magellan; and
- Brian Baldasare, the point person for Meridian in connection with its acquisition of Magellan, who is expected to testify that Magellan did not fully disclose the severity and impact of the Malfunction on LeadCare Ultra and did not disclose at all that the Malfunction impacted LeadCare II.

5. Patient harm witnesses

The government expects to call parents and treating physicians of pediatric patients who received normal blood lead test results on a LeadCare device before the recall but elevated results when retested following the recall. Potential witnesses include:

- Jared Ellis (father) and Dr. Lauren Conca (pediatrician) for patient Michael Ellis;
- Rebecca Harstad-Dallman (mother) and Dr. Nancy Dronen (pediatrician) for patient Austin Dallman; and
- Colleen Mulligan (mother) and Dr. Jeremy Warhaftig (pediatrician) for patient Simon Thomas.

For each patient, the pediatrician is expected to testify about their treatment of the patient in connection with routine blood lead testing, including the results of blood lead tests on LeadCare devices before the recall and the results of retesting on non-LeadCare devices after the recall, and the impact of those results on the pediatrician's course of treatment. The parent of each patient is

expected to testify about their observations of their child's developmental delays, the steps they took to determine and then mitigate the source of their child's lead exposure, and the additional medical treatment the child required after receiving the elevated blood lead level result on a non-LeadCare device.

In addition, the government expects to call:

- Dr. Mona Hanna-Attisha, pediatrician in Flint, MI, who discovered the lead water contamination issue and alerted the public to the problem, and who is expected to testify about her role in working with public health officials to create and execute an extensive blood lead testing program for Flint residents; and about the potential impact of Magellan's, including Winslow's, false and/or misleading statements about the accuracy of LeadCare II devices.

6. Law enforcement witnesses

The government expects to call retired Special Agent Benedict Celso of the FDA's Office of Criminal Investigations (FDA-OCI), to testify about statements that Daoust made during her first interview with him in August of 2018. The government may also call Special Agent Scott Wisnaskas of the Department of Health and Human Services Office of Inspector General (HHS-OIG), who is expected to provide testimony about the investigation of the defendants and foundational testimony for the admission of various records. SA Wisnaskas is also expected to summarize and/or read in portions of relevant records, including summaries of relevant tests and statements by the defendants.

7. Records custodians

As described below, the government will seek to introduce into evidence various email communications; internal Magellan testing protocols and results; meeting agendas, minutes and

notes; personnel files; FDA regulatory submissions and communications with FDA personnel; and other business records to prove that the defendants committed the charged crimes. These records are admissible under FRE 803(6) as records of a regularly conducted activity and/or under FRE 803(8) as public records and are self-authenticating under one or more subsections of FRE 902. While the government does not believe more is required to establish the admissibility of the offered records, the government will be prepared to introduce testimony from records custodians if required.

B. Exhibits

The government provided its exhibit list to the defendants on December 20, 2024, and will continue to revise and refine that list as it prepares for trial. Broadly speaking, the government's exhibits consist of emails, notes, text messages, calendar entries, presentations, sales data, marketing materials, device labeling, testing protocols and reports, and regulatory filings of the defendants, the defendants' coconspirators, Magellan's employees and consultants, Magellan's customers, and relevant personnel from the FDA, CDC, Meridian Bioscience, Inc., and Magellan's board of directors.

III. Charged offenses

The grand jury returned an indictment on April 3, 2023 charging defendants Winslow, Maleknia, and Daoust with conspiracy to commit wire fraud (Count One), substantive wire fraud (Counts Two and Three), conspiracy to defraud an agency of the United States (the FDA) (Count Four), and two felony violations of the Food, Drug and Cosmetics Act (FDCA) for introducing misbranded devices into interstate commerce with intent to defraud or mislead (Counts Five and Six). The elements of the charged crimes are set forth below.

A. Wire Fraud, 18 U.S.C. § 1343 (Counts Two and Three)

To prove wire fraud under § 1343, the government must prove:

1. a scheme, substantially as charged in the indictment, to defraud or to obtain money or property by means of materially false or fraudulent pretenses;

2. defendants' knowing and willful participation in this scheme with the intent to defraud; and

3. the use of an interstate wire communication, on or about the date alleged, in furtherance of this scheme.

To secure a wire fraud conviction, the government "need not prove that the decisionmaker actually relied on the falsehood, so long as the falsehood that was made is a material one. To prove materiality, the government need only show that the false statement had a natural tendency to influence, or was capable of influencing, its target's decision." *United States v. Cadden*, 965 F.3d 1, 12 (1st Cir. 2020) (cleaned up) (citing *United States v. Prieto*, 812 F.3d 6, 13 (1st Cir. 2016); *United States v. Appolon*, 715 F.3d 362, 368 (1st Cir. 2013)).

B. Conspiracy to Commit Wire Fraud, 18 U.S.C. § 1349 (Count One)

To prove a conspiracy to commit wire fraud under § 1349, the government must prove:

1. an agreement between two or more persons to commit wire fraud, substantially as charged in the indictment; and

2. the defendants willfully joined the agreement, intending that wire fraud be committed.

The government need <u>not</u> prove an overt act to secure a conviction for wire fraud conspiracy under § 1349. *See United States v. Clough*, 978 F.3d 810, 816 n.11 (1st Cir. 2020); *United States v. Iwuala*, 789 F.3d 1, 9 (1st Cir. 2015) ("To prove conspiracy to commit health-care fraud under 18 U.S.C. § 1349, the government must prove beyond a reasonable doubt that an agreement existed to commit the underlying substantive offense (here, health-care fraud under 18

U.S.C. § 1347), that the defendant knew of the agreement, and that he voluntarily joined it with the intent to commit the underlying offense.").

C. Conspiracy to Defraud an Agency of the United States, 18 U.S.C. § 371 (Count Four)

Section 371 "proscribes two different conspiracies: one to commit a specific offense, the 'offense clause,' and the other to defraud the United States 'in any manner or for any purpose,' the 'defraud clause.'" *United States v. Barker Steel Co., Inc.*, 985 F.2d 1123, 1129 (1st Cir. 1993) (quoting *United States v. Hurley*, 957 F.2d 1, 3 (1st Cir. 1992)). "The defraud clause of § 371 encompasses conspiracies that seek to interfere with government functions." *United States v. Carter*, 15 F.4th 26, 30 (1st Cir. 2021) (cleaned up).

To prove a conspiracy to defraud the United States, or any agency thereof (here, the FDA), under § 371, the government must prove:

1. an agreement between two or more persons to defraud the FDA, substantially as charged in the indictment, and

2. the defendants willfully joined the agreement, intending to defraud the FDA; and

3. one of the conspirators committed an overt act during the period of the conspiracy in an effort to further the purpose of the conspiracy.

The objective of the agreement is unlawful if it is "for the purpose of impairing, obstructing or defeating the lawful function of any department of Government." *Dennis v. United States*, 384 U.S. 855, 861 (1966) (cleaned up) (quoting *Haas v. Henkel*, 216 U.S. 462, 479 (1910)).

D. Introduction of Misbranded Devices into Interstate Commerce with Intent to Defraud and Mislead, 21 U.S.C. §§ 331(a), 333(a)(2) (Counts Five and Six)

To prove a felony violation of the FDCA for introducing or causing the introduction of a misbranded medical device into interstate commerce, the government must prove:

1. the defendants introduced or caused to be introduced into interstate commerce the medical device described in the indictment;

2. this medical device was misbranded at the time of its introduction; and

3. the defendants acted with intent to defraud or mislead.

Count Five alleges that the LeadCare Ultra and LeadCare II devices were misbranded because they were distributed to customers outside Massachusetts even though necessary medical device reports (MDRs) reporting product malfunctions had not been filed with the FDA.

Count Six alleges that the LeadCare Ultra and LeadCare II devices were misbranded because they were distributed to customers outside Massachusetts with instructions to incubate the blood-treatment reagent samples for 24 hours, even though (i) the defendants failed to provide the FDA pre-market notification at least 90 days before distributing a significantly changed device and (ii) the defendants did not file the necessary reports of device correction initiated to reduce a risk to health posed by the device.

IV. Evidentiary Issues

A. Preadmission of business and public records under FRE 803

As noted above, the government intends to prove the charged crimes with evidence that includes various emails, notes, calendar entries, presentations, sales data, marketing materials, device labeling, testing protocols and reports, and regulatory filings. These materials are admissible under the hearsay exception for records of regularly conducted activity pursuant to FRE 803(6). The government will introduce certifications pursuant to FRE 902(11) for these business records. The government also may introduce certain public records under FRE 803(8). Rule 803(8) provides an exception to the hearsay rule for public records from a public agency or office, relating to an activity of the office. "Records kept . . . [b]y public agencies may be admissible under the business records exception, Fed. R. Evid. 803(6), as well as under the public records exception, Fed. R. Evid. 803(8)." *United States v. Bohrer*, 807 F.2d 159, 162 (10th Cir. 1986) (internal

citations omitted). Because these records are self-authenticating under one or more subsection of FRE 902, the government intends to seek their admission into evidence prior to the start of trial.

B. Summaries of voluminous records under FRE 1006

The government may seek to admit exhibits that summarize voluminous medical and business records. These "summary tools" are admissible "to clarify complex testimony and evidence" under FRE 1006. *See United States v. McElroy*, 587 F.3d 73, 81 (1st Cir. 2009); *see also Appolon*, 695 F.3d at 61–62 (1st Cir. 2012) (affirming admission of summary exhibits that obviated the need for "the jury to sift through mortgage and sale records for each of the twenty-one properties involved in appellants' scheme and also facilitated tracing the scheme's proceeds") (cleaned up). Summary exhibits are admissible either individually or in addition to the underlying records. *United States v. Milkiewicz*, 470 F.3d 390, 396–97 (1st Cir. 2006) ("While in most cases a Rule 1006 chart will be the *only* evidence the fact finder will examine concerning a voluminous set of documents, in other instances the summary may be admitted *in addition to* the underlying documents to provide the jury with easier access to the relevant information.") (cleaned up). And the government may also elicit testimony to describe and explain the summary exhibits. *McElroy*, 587 F.3d at 81 ("[S]ummary witness testimony may be permitted pursuant to Rule 611(a).") (citing *Milkiewicz*, 470 F.3d at 397–98 and *United States v. Stierhoff*, 549 F.3d 19, 27–28 (1st Cir. 2008)); *Appolon*, 695 F.3d at 63 (affirming introduction of summary witness testimony where testimony "was limited to introducing and explaining the summary charts [the summary witness] prepared").

C. Expert testimony under FRE 702

As previously briefed and discussed at the *Daubert* hearing on January 23, 2025, the government intends to present testimony from Dr. Courtney Lias (FDA) and Dr. Adrienne Ettinger (CDC) pursuant to FRE 702 (in addition to certain fact and lay opinion testimony). The parties

will meet and confer before the next scheduled *Daubert* hearing on February 10, 2025 in an effort to reach agreement about the admissibility of opinions offered by Dr. Lias, Dr. Ettinger, and the defense experts, Dr. William Banner and Phillip Phillips. The government understands that the Court may also consider testimony from certain former Magellan scientists and consultants to fall within the scope of Rule 702. Accordingly, the government will supplement its prior disclosure of those witnesses' anticipated testimony with their CVs and publications.

D. Lay opinion testimony under FRE 701

In addition to the expert testimony just discussed, the government expects to offer lay opinion testimony from other, non-scientist Magellan employees, Magellan customers, FDA personnel, and treating pediatricians pursuant to FRE 701. In addition to providing fact testimony regarding their relevant work experience, use of LeadCare devices in labs and at the point of care, review of and communications with Magellan about its regulatory submissions regarding the Malfunction, and/or routine treatment of patients, the government expects these witnesses will give lay opinion testimony related to the expected performance of the LeadCare devices, interpretation of information provided in regulatory filings, and/or medical treatment decisions. In each case, the opinion testimony will be grounded in their personal, on-the-job experience and based on the kinds of logical inference available to the average person (*e.g.*, that a blood lead test result should be constant and not increase over time, or that the failure of a medical device to perform to its label specifications is a "malfunction," or that a pediatrician would make decisions about how to treat a patient depending on the patient's blood lead level).

Such testimony is properly considered lay opinion testimony and is admissible under FRE 701. In *United States v. Galatis*, the First Circuit upheld the admission of testimony from employees of a home health agency that included the witnesses' opinions about whether their patients were "homebound" and in need of "skilled nursing" services, finding that "testimony to a

witness's understanding of regulatory language can be included pursuant to FRE 701 if it does not seek to offer a conclusive commentary on the law's meaning and is the product of a reasoning process accessible to the average person." 849 F.3d 455, 461 (1st Cir. 2017). The lay opinion testimony of all of these witnesses will no doubt be subject to reliability testing through vigorous cross-examination, effectively mitigating any issue with allowing the testimony. *See id.* (holding that the properly admitted lay opinion testimony was "susceptible to cross-examination"); *United States v. Ayala-Pizarro*, 407 F.3d 25, 28 (1st Cir. 2005) (same).

E. Co-conspirator statements under FRE 801(d)(2)(E)

The charges in this case include conspiracy to commit wire fraud and conspiracy to defraud an agency of the United States (the FDA). For the reasons set forth in the motion in limine filed with the Court today, the government seeks to introduce the out-of-court statements of the defendants' co-conspirators pursuant to FRE 801(d)(2)(E). As noted in the government's motion, the out-of-court statements of the defendants and their co-conspirators may also be admissible under FRE 801(d)(2)(A)-(D) and under one or more of the exceptions to hearsay set forth in FRE 803. For example, the defendants' statements, if offered by the government, are non-hearsay because they are statements of a party opponent. Fed. R. Evid. 801(d)(2)(A). The government may also introduce statements, whether oral or written, of third parties to provide necessary context or background to understand the defendants' statements. *See, e.g.*, *United v. Page*, 521 F.3d 101, 106 (1st Cir. 2008); *United States v. Catano*, 65 F.3d 219, 225 (1st Cir. 1995).

F. Evidence of other acts intrinsic to the fraud scheme or under FRE 404(b)

The government disclosed to the defendants on December 20, 2024 its intent to introduce evidence of other acts intrinsic to the fraud scheme and/or admissible under FRE 404(b). Specifically, the government seeks to introduce evidence concerning the defendants' decision to

file an MDR for two instances of false low reporting of blood lead values by LeadCare II devices in 2013 due to reasons unrelated to the Malfunction at issue in this case. Under Rule 404(b), evidence of other acts "may be admissible for another purpose, such as proving motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident." Fed R. Evid. 404(b)(2). In this case, evidence of prior compliance with the MDR reporting regulations is relevant to prove the defendants' knowledge of the law, absence of mistake or accident, opportunity to file an MDR, intent to mislead and defraud in connection with the delayed filings over the Malfunction, and a motive and plan to delay filing when there was no root cause or effective mitigation in place. *See, e.g.*, *United States v. Scali*, 2018 WL 461441, at *5–6 (S.D.N.Y. Jan. 18, 2018) (evidence of defendant's tax filing history admissible to prove "willfulness and corrupt intent"); *United States v. Gilmartin*, 684 F. App'x 8, 11 (2d Cir. 2017) (summary order) ("[C]ertain facts can support an inference that a defendant willfully violated his duty to obey tax laws, including the defendant's prior taxpaying record.").

The government may also introduce evidence that the defendants provided false and misleading information to, and withheld material information about the nature and extent of the Malfunction from, Meridian Bioscience, Inc., in connection with Meridian's acquisition of Magellan in 2016. This evidence is intrinsic to the crimes charged as it is relevant to the defendants' motive to defraud customers and the FDA, namely, to avoid anything that could interfere with or scuttle a possible sale of the company or adversely affect the price another company would be willing to pay to acquire Magellan. *See, e.g.*, Indictment ¶¶ 1, 31–33. It is well-settled that evidence of other acts that are "intrinsic to the crime for which the defendant is on trial" is admissible without regard for the requirements of Rule 404(b). *United States v. Epstein*, 426 F.3d 431, 439 (1st Cir. 2005) (citation and internal quotation marks omitted) (affirming

admission of defendant's tax return because the return was "intertwined with the crime" insofar as it reported some of the income he received from the wire fraud scheme, but not all of it, suggesting knowledge of the fraud); *United States v. Taylor*, 284 F.3d 95, 101 (1st Cir. 2002) (affirming admission of reference to defendant's prior drug transaction on consensual recording with cooperating witness "as part and parcel of an on-going conversation taking place during the crime itself," and citing *United States v. Kennedy*, 32 F.3d 876, 885 (4th Cir. 1994), for the proposition that "Rule 404(b) is not applicable to evidence of crimes that are necessary to complete the story of the charged crime"). Here, this evidence is essential to complete the story of the charged crime. It is also, in any event, equally admissible under Rule 404(b) as evidence of the defendants' motive, intent to defraud, preparation, plan, knowledge, and absence of mistake or accident.

G. Advice of counsel defense

The Court has ordered the defendants to inform the government whether they intend to rely on advice or involvement of counsel by February 10, 2025 (Dkt. 200). If the defendants do intend to do so, they must disclose to the government any materials or information they expect to offer or otherwise rely upon in support of such a defense. *See* Dkt. 187. In the event Magellan asserts the attorney-client privilege, the Court may need to review the materials *in camera* and decide whether the defendants' constitutional rights take precedence over Magellan's entitlement to the privilege. If the Court rules in the defendants' favor, the government will need time to review the materials in advance of trial.

H. Self-serving hearsay of defendants

As discussed in the motion in limine filed today, the government will object to any attempt by the defendants to offer their own out-of-court statements to prove the truth of the matter asserted as inadmissible hearsay. Unlike the government, the defendants may not offer or elicit their own

prior statements at trial because those statements are hearsay as to them. *United States v. Rivera-Hernandez*, 497 F.3d 71, 80 (1st Cir. 2007). The defendants are not permitted to circumvent this rule by eliciting their own statements through the cross-examination of other witnesses. *United States v. Bauzo-Santiago*, 49 F. Supp. 3d 155, 157–58 (D.P.R. 2014) (prohibiting defendant from eliciting defendant's "out-of-court statement during cross-examination of government witnesses to impeach the witnesses") (citing *Bemis v. Edwards*, 45 F.3d 1369, 1372 (9th Cir. 1995) and *United States v. Hudson*, 970 F.2d 948, 956 (1st Cir. 1992)). Further, merely because the government presents only a subset of the defendants' out-of-court statements, the defendants are not entitled to present other statements under the rule of completeness absent a need to avoid "misunderstanding or distortion." *United States v. Simonelli,* 237 F.3d 19, 28 (1st Cir. 2001) (rule of completeness "does not permit the admission of otherwise inadmissible evidence simply because one party has referred to a portion of such evidence, . . . rather, it operates to ensure fairness where a misunderstanding or distortion created by the other party can only be averted by the introduction of the full text of the out-of-court statement").

V. Stipulations

The government will meet and confer with the defendants in an effort to reach agreement regarding the admission of evidence and any other matters that can be resolved by stipulation.

VI. Defense Case

The defendants have indicated that they intend to put on an affirmative case at trial and they produced their witness and exhibit lists to the government on January 10, 2025. The government has requested reciprocal discovery and reverse *Jencks* material for the individuals on the defense witness list, pursuant to Fed. R. Crim. P. 26.2, but the defense has not yet produced

any such material. The government is entitled to receive, and the defendants are obligated to produce, these materials.

To the extent the defendants introduce evidence or testimony in their defense case, the government requests the opportunity to rebut such newly presented evidence or argument and requests permission—if necessary—to recall witnesses to testify about the defense evidence.

VII. Other matters

A. Nullification arguments

As set forth in the motion in limine filed today, the government will object to questions or arguments from the defendants that call for jury nullification. As an example, the government will object to questions or arguments aimed at persuading the jury that the defendants should not be found guilty of the crimes charged in the indictment because Becton Dickinson's reformulation of its test tube stopper contributed to the Malfunction. The government also will object to questions or arguments aimed at jury bias against government bureaucracy or inefficiency, particularly with respect to the FDA or CDC. Likewise, the government will object to questions or arguments concerning the defendants' personal or family circumstances and the potential punishment or other consequences they face if convicted or have faced as a result of being charged.

B. Corporate resolution

As the Court is aware, Magellan Diagnostics, Inc. was convicted of FDCA device misbranding charges and ordered to pay a $21.8 million criminal fine and $10.9 million in forfeiture. *United States v. Magellan Diagnostics, Inc.*, 24-cr-10146-PBS (Dkt. 15, 24). Pursuant to a deferred prosecution agreement (DPA), Magellan also is required to pay no less than $9.3 million to compensate patients who suffered economic harm caused by prolonged lead exposure and delayed detection of lead poisoning due to the Malfunction and to retain a corporate monitor

to oversee its FDA regulatory compliance program and its victim compensation obligations. *United States v. Magellan Diagnostics, Inc.*, 24-cr-10144-PBS (Dkt. 4). The parties have agreed to avoid any reference to the fact of Magellan's conviction, the terms of its punishment, or the company's compliance and victim compensation obligations under the DPA.

C. Case agents in courtroom

With the Court's permission, the government asks that case agents and potential witnesses Scott Wisnaskas (HHS-OIG) and Benedict Celso (FDA-OCI, retired) be permitted to sit in the courtroom during the testimony of other witnesses. Other agents from HHS-OIG, FDA-OCI, and the FBI will be helping to coordinate the timing of witnesses' appearance and to ensure that the next witnesses are ready to testify. The government expects those agents will be in and out of the courtroom for this purpose.

D. Electronic presentation of evidence

With the Court's permission, the government intends to present its audio-visual and documentary evidence in electronic format using the Trial Director or another similar trial management software program. The government anticipates that a paralegal with the U.S. Attorney's Office will operate the trial management program.

E. Use of PowerPoint Presentation

With the Court's permission, the government intends to use PowerPoint presentations during its opening statement and closing argument, which will allow for a more organized presentation of the anticipated evidence and summation of the evidence in this case.

F. Demonstrative exhibits

In its case-in-chief, the government intends to offer various demonstrative exhibits, such as timelines, graphic representations of relevant information, and the LeadCare devices

manufactured by Magellan during the relevant time. Such demonstrative exhibits will aid the jury in understanding the background and context for the evidence and testimony presented and will not be offered into evidence.

Respectfully submitted,

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CERTIFICATE OF SERVICE

Undersigned counsel certifies that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Kelly Begg Lawrence
Kelly Begg Lawrence
Assistant United States Attorney

Dated: January 30, 2025